multi-million dollar overpayments made by Plaintiffs and Class members. *See* ¶¶ 644-46, 677-79; Plaintiffs' Opp. at 32-38. Because, in this Circuit, there is no "reliance" requirement (even when the predicate acts are mail and wire fraud), *see id.* at 33-35 (discussing *Sebago, Inc. v. Beazer East, Inc.*, 18 F. Supp. 2d 70 (D. Mass. 1998)), Plaintiffs' allegations satisfy the RICO "causation" tests established by the Supreme Court in *Holmes v. Securities Investor Protection Corp.*, 503 U.S. 258 (1992).

Defendants' response to Plaintiffs' opposition brief on standing issues is classically diversionary. Plaintiffs proffered an extensive analysis of why their RICO claims satisfy the "causation" tests laid down by the Supreme Court in *Holmes*, 503 U.S. at 273, including a rebuttal of Defendants' "intervening causes" argument. *See* Plaintiffs' Opp. at 35-38. In sum, the first *Holmes* inquiry favors Plaintiffs because damages will not be difficult to prove. Defendants determine the reimbursement base ***directly*** by setting the AWP, and Plaintiffs set forth mathematical damage examples based on allegations in the AMCC, yet Defendants chose to entirely ignore these examples in their reply. *See* Plaintiffs' Opp. at 35-36. Turning to the second *Holmes* inquiry, damages will not need to be apportioned among Plaintiffs and Class members who have been harmed by the same injury, because the direct injuries here are uniquely incurred by each Plaintiff and Class member. *See id.* at 36. Finally, considering the third *Holmes* factor, no other party has been more directly injured, because no one else has suffered the co-pay injury or the injuries suffered by the third-party payor Plaintiffs. *See id.* at 36-37. Indeed, Defendants recognized in their own documents that the practice of AWP inflation would be directly felt by the precise class on whose behalf the claims are asserted in this case:

> ***Private insurers, out of pocket payors: these groups and perhaps others, are likely to incur greater costs as a result of this pricing strategy.***

¶ 395 (emphasis added). And this admission of direct harm identifies ***no*** intervening causes of harm, but admits the existence of a direct link between AWP inflation and injury to the precise class in this case.

Defendants make no attempt to contradict Plaintiffs' lengthy *Holmes* "causation" analysis, merely stating in conclusory fashion that Plaintiffs' theory is contrary to *Holmes*. *See* Defs. Reply at 11-13. Defendants have failed to explain why *Holmes* is contrary, because they are unable to effectively explain how the *Holmes* factors favor dismissal. Nor do Defendants even attempt to explain away Defendant Glaxo's written admission that "government," "[p]rivate insurers, out-of-pocket payers" and "others ... are likely to incur greater costs as a result of" increasing "the AWP for Zofran in order to increase the amount of Medicaid reimbursement for clinical oncology practices." *Id.*

Ignoring appellate court decisions previously cited by Plaintiffs, *see* Plaintiffs' Opp. at 33, Defendants argue that the civil RICO claims cannot succeed because "defendants made no representations directly to [plaintiffs]" and class members, Defs. Reply at 12, even though the AMCC "alleges that Plaintiffs and Class members are the ***targets*** of Defendants' AWP Scheme." Plaintiffs' Opp. at 32 (emphasis added) (citing AMCC, ¶ 3). This is a red herring, and Defendants can only advance this argument by ignoring numerous circuit court decisions to the contrary. *See, e.g.*, *Commercial Cleaning Servs., L.L.C. v. Colin Serv. Sys., Inc.*, 271 F.3d 374, 384 (2d Cir. 2001) (reversing dismissal of civil RICO claim on standing grounds where plaintiff was injured by competitor's illegal permitting of illegal aliens, thus permitting defendant to underbid plaintiff) (cited in Plaintiffs' Opp. at 33); *Baisch v. Gallina,* 2003 U.S. App. Lexis 20127, at *17 (2d Cir. Oct. 2, 2003) (stating that under RICO's causation analysis, "the reasonably foreseeable victims of a RICO violation are typically limited to the targets, competitors and intended victims of the racketeering enterprise" (quoting *Lerner v. Fleet Bank, N.A.*, 318 F.3d 113, 124 (2d Cir. 2003)). These courts do not require that the representations be direct. And Defendants' argument ignores the AMCC's allegations that the Plaintiffs paid for their drugs based on inflated AWP's which "directly" caused injury. ¶¶ 139-40.

Defendants also ignore the Supreme Court's mandate that "RICO is to be read broadly. This is the lesson not only of Congress' self-consciously expansive language and overall

approach, but also of its express admonition that RICO is to be liberally construed to effectuate its remedial purposes." *Sedima, S.P.R.L. v. Imrex Co.*, 473 U.S. 479, 497-98 (1985) (citations and quotation marks omitted).

Defendants' attempt to distinguish *Sebago* likewise falls short. Defendants claim that *Sebago* did not involve any intervening actors, Defs. Reply at 13, but this is false, as the current owners of the building were not the original owners. 18 F. Supp. 2d at 83. And, notably, Defendants do not take issue with *Sebago*'s holding that "it is for a jury [to] apply the law of proximate causation and decide whether the plaintiffs were in the zone of foreseeable plaintiffs and whether the defendants' actions were a substantial factor in causing the plaintiffs' harm." *Id.* at 85 (collecting cases).

To reiterate, because Defendants directly set the reimbursement base (the AWP), every Plaintiff and Class member is directly harmed. ¶¶ 3, 139-40. It is immaterial that Defendants make the AWP misrepresentation to third-party publishers and not to Plaintiffs, that the prescribing doctor and not the patient submits claims for reimbursement, that Congress chose to base reimbursements on AWP instead of some other formula, and that PBMs, not the Defendants, contract with the health plans. None of these events detract from the direct injury inflicted upon Plaintiffs and the Class by Defendants' direct AWP reporting. The Court should reject Defendants' standing/causation challenge.

**C. Plaintiffs State A Claim For Civil Conspiracy**

In their reply, Defendants do not contest that Massachusetts law defining a claim for a concerted action conspiracy governs Plaintiffs' claim. Instead, Defendants focus their attack on purported Rule 9(b) deficiencies in the AMCC. But the AMCC sets forth the circumstances of the conspiracy. For instance, not only does the AMCC detail the allegations of each Defendant's inflated AWPs, it describes how, as fiscal intermediaries between Defendants and health plans and their participants, PBMs: (i) use inflated AWPs set by Defendants as the basis for reimbursement; (ii) pocket the spread or differential between the Pharmacy Reimbursement and

the Health Plan Payments; and (iii) are encouraged to place on their formularies the drugs with the most inflated AWPs. *See, e.g.*, ¶¶ 168-76. These allegations are sufficient to apprise Defendants of "the circumstances of the fraud," and Plaintiffs are "not required to plead all of the evidence or facts supporting it." *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 46-47 (D. Mass. 2001).

Nonetheless, in an attempt to circumvent *Parke-Davis*, Defendants cite to *Doyle v. Hasbro, Inc.*, 103 F.3d 186 (1st Cir. 1996). *Doyle*, however, demonstrates that Plaintiffs have, in fact, satisfied the pleading requirements. Dismissing a fraud claim, the *Doyle* court noted that:

> The complaint simply states that the defendants ... worked closely together and were aware of the others' conduct. These defendants conspired to use H.P. Leasing for the benefit of Hasbro and their own personal financial gain. It is not certain what the specifics of the conspiracy entailed or how exactly defendants Thibideau [sic] and Hassenfeld benefited from that conspiracy.

*Id.* at 194. Defendants here can hardly claim that the *Doyle* complaint is analogous to Plaintiffs' AMCC. Here, unlike in *Doyle*, Plaintiffs allege the mechanisms of the conspiracy, the inflated AWPs around which the conspiracy was built and how both the PBMs and Defendants benefited from the conspiracy.

Similarly, Defendants' reliance on *Aetna Cas. Sur. Co. v. P&B Autobody*, 43 F.3d 1546, 1564 (1st Cir. 1996), and *Herring v. Vadala*, 670 F. Supp. 1082, 1087 (D. Mass. 1987), is misplaced. In *Aetna*, the First Circuit affirmed the district court's entry of judgment against defendants, holding that the evidence supported the jury's liability finding under RICO and civil conspiracy counts. Thus, and contrary to Defendants' inference, *Aetna* stands for the proposition that Plaintiffs can recover for civil conspiracy, in addition to their remaining claims. Furthermore, the First Circuit in *Aetna* made clear that defendants will be held liable where there is "first, a common design or an agreement, although not necessarily express, between two or more persons to do a wrongful act and, second, proof of some tortious act in furtherance of the agreement." *Aetna*, 43 F.3d at 1564. Plaintiffs allege both prongs here.

Defendants also claim that the fact each conspiracy operated in an identical fashion mandates dismissal. Defs. Reply at 13. But Defendants are wrong. As the AMCC makes clear, the industry has set itself up to operate in a common fashion whereby each manufacturer defendant transmits phony AWPs, which are then reported by the co-conspirator publishers, and each of the four major PBM co-conspirators are provided incentives for marketing the spread. The fact that the manufacturers operate on parallel and similar tracks with respect to each Defendant-publisher or Defendant-PBM co-conspirator, does not for a second negate the existence of each conspiracy. For example, AstraZeneca has admitted that it provided an AWP spread to one PBM in order to obtain its business and that the cost would be passed onto the patient or third-party payor. ¶ 236. The fact that the scheme worked in the same fashion with other Defendants, does not defeat this claim. Nor does the fact that there are many such conspiracies.

Nor does *Herring* support Defendants' position. In *Herring*, the court dismissed the fraud claims pursuant to Rule 9(b) because the plaintiff was, *inter alia*, "intimately involved" in all the transactions about which he complained. In contrast, Plaintiffs here are not involved in the manipulation of AWPs by Defendants and the deal-making between Defendants and the PBMs that resulted in the PBMs' use of inflated AWPs as reimbursement benchmarks in exchange for garnering spreads at the expense of Plaintiffs and the Class.

Finally, Defendants argue that Massachusetts law does not support a conspiracy action when the unlawful conduct leads to additional claims. Defs. Reply at 14. This argument is directly contrary to *Queeno v. Cote*, 1999 Mass. Super. Lexis 506 (Dec. 30, 1999), in which the court held that "a fraud, if proven, may be the basis for several forms of relief by an aggrieved person." *Id.*, at *9. Defendants' attempt to distinguish *Queeno* fails. They argue that *Queeno* did not sustain separate causes of action, but required that the fraud allegations be read with the civil conspiracy charge. *See* Defs. Reply at 15 n.12. But Defendants' recital of the *Queeno* holding is incomplete. While the court stated that the fraud count had to be read with the civil conspiracy

count in order to show that the combination was for unlawful means, *id.* at *8, at no time did the *Queeno* court reach the conclusion that separate causes of action flowing from the same illegal conduct could not be sustained.

The AMCC appropriately alleges a combination between each Defendant and a PBM for the wrongful purpose of perpetuating a reimbursement system based on fraudulently-overstated AWPs. ¶¶ 168-76, 729. The details presented in these paragraphs belie the "conclusory" allegations moniker advanced by Defendants. The civil conspiracy allegations comport with Rule 9(b) and are consistent with civil conspiracy jurisprudence from this commonwealth. Defendants' effort to dismiss Count IX should be rejected.

**D. Plaintiffs' Consumer Fraud Claims Should Be Sustained**

In their reply, Defendants attack Plaintiffs' state law claims on three grounds. First, Defendants again contend that the AMCC fails to plead causation because intervening third parties such as PBMs and medical providers also contributed to the deception. *See* Defs. Opening Br. at 29-30; Defs. Reply at 15. However, as Plaintiffs demonstrated in their opposition, this argument is unavailing because the third parties merely did as they were directed (to obtain Defendants' incentives), and thus advanced – but did not break – the foreseeable chain of causation designed and intended by Defendants. *See* Plaintiffs' Opp. at 44. Indeed, to find otherwise would lead to the absurd result that even if Defendants admitted that they reported fraudulently inflated AWPs (and they never have denied it, but instead essentially claim as a defense that everyone "knew we did it"), they could never be held liable because of the involvement of these same so-called intervening parties.

Defendants also errantly argue that Plaintiffs have "effectively concede[d]" that they were not influenced by Defendants' allegedly fraudulent conduct. Defs. Reply at 15-16. This is untrue, and the argument seeks to impose a "back door" reliance requirement that does not exist. As Plaintiffs have explained, the test for whether Defendants' conduct is unfair or deceptive is whether their practices have a ***tendency*** or ***capacity*** to deceive. *See* Plaintiffs' Opp. at 45 n.28

and the cases cited therein. In demonstrating that Defendants' practices have the tendency or capacity to deceive, Plaintiffs need not allege and prove that they were aware of the AWPs for each drug prescribed for them. Indeed, a lack of knowledge regarding AWPs would only ***strengthen*** Plaintiffs' claim, as it facilitates the likelihood that Defendants' deception would succeed.[8]

Furthermore, reliance is not an element of the cause of action under any of these state consumer protection acts – including Pennsylvania's "catch-all" UTPCPL § 201-2(v)(xxi), which was recently amended to differentiate "deceptive" conduct from "fraudulent" conduct. *See* Plaintiffs' Opp. at 51 & n.31. And in their zeal to fabricate a reliance requirement under the New York statute, Defendants overlook *Blue Cross & Blue Shield of N.J., Inc. v. Phillip Morris*, 178 F. Supp. 2d 198 (E.D.N.Y. 2001), *rev'd in part on other grounds*, 2003 U.S. App. Lexis 19155 (2d Cir. Sept. 16, 2003), which held that the act ***eliminated*** the traditional requirements of reliance and scienter. *Id.* at 231. Defendants attempt to distinguish *Phillip Morris* by stating that it addresses the pleading requirements of General Business Law § 349, yet Plaintiffs bring their claims under § 349.[9]

Moreover, even if Plaintiffs were required to expressly allege that they relied on Defendants' fraudulent AWPs, they have done so, particularly with respect to the third-party payor Plaintiffs. *See, e.g.*, ¶¶ 461 ("This same flow chart then shows that third party payors rely on these industry compendia for prices."); ¶¶ 633(f), 730(g) (stating that Defendants made,

[8] To the extent that Defendants interpret Plaintiffs' statement that "Plaintiffs did not decide to purchase drugs based on prices listed in the *Red Book*" (*see* Plaintiffs' Opp. at 45-46) as an admission that Plaintiffs did not purchase drugs for which pricing was based on AWP, this is not the meaning of the sentence. The proper interpretation of that phrase is that a patient's purchase decision was not based on the reported AWPs; rather, Plaintiffs' point was that patients buy drugs that are prescribed by their physicians because they want to treat their illness or condition – not because of an AWP reported by *Red Book*. Therefore, Plaintiffs have hardly admitted that no deception regarding pricing has occurred.

[9] To be sure, Plaintiffs also bring their claims under New York Gen. Bus. Law § 350, but New York courts have indicated that reliance may be presumed under § 350 where, like here, Plaintiffs had no way of knowing of the nature and extent of the deceptive conduct. *See Sabater v. Lead Indus. Ass'n*, 183 Misc. 2d 759, 770, 704 N.Y.S.2d 800, 808 (N.Y. Sup. Ct. 2000) (suggesting that reliance may be presumed under § 350, except in the situation "where plaintiffs had a reasonable opportunity to discover the facts about the transaction beforehand by using ordinary intelligence").

"[w]ritten and oral communications with health insurers and patients, including Plaintiffs and members of the Class, inducing payments for the drugs that were made in reliance on AWPs"); ¶ 639 ("In designing and implementing the AWP scheme, at all times the Defendant Drug Manufacturers were cognizant of the fact that those in the distribution chain who are not part of the industry rely on the integrity of the Defendant Drug Manufacturers in setting the AWPs, as reported by the Publishers."); ¶¶ 645, 678 ("Plaintiffs and members of the Classes have made inflated payments for AWPIDs based on and/or in reliance on reported and false AWPs."); ¶ 688 ("Defendants willfully engaged in such practices knowing them to be deceptive and with the intent that Plaintiffs and the Class would rely thereon."); ¶ 691 "As a direct and legal result of Defendants' misleading, deceptive, unfair, false and fraudulent trade practices, Plaintiffs and the Class have sustained injuries.").

Lastly, Defendants continue to assert that Plaintiffs lack standing under the consumer protection statutes, yet their reply arguments add nothing and certainly do not support dismissing any state consumer claims based on standing issues. For example, Defendants cite *Coastal Physician Servs., Inc. v. Ortiz*, 764 So.2d 7, 8 (Fla. 4th Dist. Ct. App. 1999) for the proposition that non-Florida residents cannot bring claims under the Florida DUTPA. Defs. Reply at 16. However, *Ortiz* was recently discredited by *Millennium Comms. & Fulfillment, Inc. v. Office of the AG, Dep't of Legal Affairs*, 761 So.2d 1256, 1261-62 (Fla. Ct. App. 2000), which rejected *Ortiz* "as it applies to the FDUTPA" in light of (i) the express language of Section 501.202, and (ii) the same appellate district's subsequent decision in *Renaissance Cruises, Inc. v. Glassman*, 738 So. 2d 436 (Fla. 4th Dist. Ct. App. 1999), applying the FDUTPA "to both in-state and out-of-state residents in a class action." *Millennium*, 761 So.2d at 1261-62. Thus, the *Millennium* court found, "it appears to us that the fourth district has receded, *sub silentio*, from its earlier holding in *Ortiz*." *Id.* at 1262.

Defendants' arguments under Louisiana law fare no better. They argue that only consumers and business competitors have standing under the Louisiana UTPA, because the Fifth

Circuit and two Louisiana district courts have concluded similarly. Defs. Reply at 16 n.16. However, Defendants ignore many Louisiana decisions repeatedly holding that business consumers and competitors are not the only parties that have a private right of action under the clear language of the Act. *See, e.g., Capitol House Preservation Co. v. Perryman Consultants, Inc.*, 725 So.2d 523, 530 (La. App. Ct. 1998) (citing cases and stating "[i]f a plaintiff alleges facts sufficient to classify himself as a member of the group provided a remedy by [the statute], it is of no moment if plaintiff is not a consumer or a business competitor of defendant"). Moreover, the Fifth Circuit's narrow interpretation of standing under the Act has been called into serious doubt by Louisiana federal district courts, which admittedly adhere to Fifth Circuit precedent because, unlike the present Court, they are obligated to do so. *See Hamilton v. Business Partners, Inc.*, 938 F. Supp. 370, 372 (E.D. La. 1996) (providing lengthy discussion because "the seminal Louisiana case upon which subsequent jurisprudence relied may well be flawed"); *5-Star Premium Fin., Inc. v. Wood*, 2000 WL 1532896, at *1 (E.D. La. Oct. 16, 2000) ("In light of the expansive language offered by the Louisiana Court of Appeals in [*Capitol House*], reconsideration of the Fifth Circuit position regarding LUPTA may be appropriate."). Because the Fifth Circuit's precedent on the issue is not binding here, the Court may follow the more logical reasoning of the Louisiana appellate courts.

Defendants' interpretation of Washington law is also wrong. Defendants cite two insurance cases, *Transamerica Title Ins. Co. v. Johnson*, 693 P.2d 697 (Wash. 1985), and *Tank v. State Farm Fire & Cas. Co.*, 715 P.2d 1133 (Wash. 1986), for the proposition that Plaintiffs do not have standing under the Washington Act because they are not direct purchasers of the drugs. Defs. Reply at 17 n.19. Defendants' cases are inapposite because unlike in *Johnson* and *Tank*, the end-payor Plaintiffs were directly harmed by Defendants' conduct when they overpaid for drugs as a result of the illegally inflated AWPs reported by Defendants. Indeed, Washington courts do not even require that the injured party be the same party that purchased the goods or services to have standing under Washington's consumer protection statute. *See, e.g.,*

*Westminster Lane Road Ass'n v. Canning*, 1999 WL 355830, at *4 (Wash. App. Ct. June 3, 1999). And, in raising a similar argument under New Jersey law, Defendants conveniently ignore *Desiano v. Warner-Lambert Co.*, 326 F.3d 339 (2d Cir. 2003), which is most directly on point, noting that insurers had long been able to recover from drug companies amounts overpaid due to illegal or deceptive marketing practices. *Id.* at 349-50.

Defendants' arguments against application of the state consumer protection laws to Defendants' deceptive conduct should be rejected.

### E. Defendants' Fraud Involving Multiple-Source Drugs Falls Squarely Within The AWP Inflation Scheme

Defendants raise several meritless arguments in their continued defense of multiple-source drug AWP inflation. The linchpin of their argument, in direct contradiction to the AMCC's allegations, is that AWP inflation does not matter – in other words, inflating AWPs does not inflate reimbursements for multiple source drugs within Medicare Part B or in the private payor context. As demonstrated in the AMCC, Plaintiffs' opposition brief (*see* pages 52-58) and again below, AWP inflation by generic manufacturers causes over-reimbursement within Medicare Part B and in private insurance systems.

#### 1. Generic Drug Reimbursement Fraud Occurs within Medicare Part B

Defendants continue to insist that Medicare Part B reimburses for multiple-source drugs "at a flat rate" and that therefore no AWP inflation fraud can occur within Medicare. Defs. Reply at 17-18.[10] This is simply not true. As the AMCC explains, the regulatory regime provides that "under Medicare Part B the AWP is equal to the less[e]r of the median AWP of all of the generic forms of the drug or biological, or the lowest brand name product AWP." ¶ 184. This is precisely what the regulation cited by Defendants provides. *See* 42 C.F.R. § 405.517(c) ("For multiple-source drugs and biologicals, ... the average wholesale price is defined as the lesser of the median average wholesale price for all sources of the generic forms of the drug or

[10] This common argument is repeated throughout the Defendants' so-called "specific" memoranda. *See, e.g.*, Abbott Section I-II, Baxter at 2; B. Braun at Section III, BMS at 1-2; Dey at Section II.

biological or the lowest average wholesale price of the brand name forms of the drug or biological."). ***Nothing*** in this regulation invokes Defendants' fictitious "flat rate."

Furthermore, there can be no doubt that inflated AWPs for generic drugs ***cause*** inflated Medicare drug reimbursements and inflated co-pays made by Medicare Part B participants. As the AMCC explains, "an individual Defendant's reported AWP for a multi-source drug raises the median AWP at which the generic drug is reimbursed." ¶ 186. Thus, there is a direct link alleged in the AMCC between raising a generic AWP and causing inflated reimbursements within Medicare Part B.[11] This is not just Plaintiffs' theory; it is shared by the OIG, which found in 1998:

> There is evidence that high-priced generic drugs have a significant financial impact on Medicare and Medicaid reimbursement. We found that inclusion of higher-priced generic drugs in Medicare payment calculations can raise allowances above the price of brand-name drugs.

DHHS OIG, THE IMPACT OF HIGH-PRICED GENERIC DRUGS ON MEDICARE AND MEDICAID at 9 (July 1998) (hereinafter "IMPACT OF HIGH-PRICED GENERIC DRUGS ON MEDICARE"). The OIG study specifically found that higher-priced generic drugs increased Medicare reimbursements because the higher-priced generic drugs were included in the median calculation. *Id.* at ii. Historically, "[w]hen the median generic policy was implemented, generic prices were normally less than those of the brand-name product." *Id.* "However," the OIG observed, "what may have originally been a cost-saving mechanism has, for certain categories of drugs, become a losing proposition." *Id.*[12]

In addition to IMPACT OF HIGH-PRICED GENERIC DRUGS ON MEDICARE, many other OIG and DHHS studies, cited throughout the AMCC and in Plaintiffs' opposition brief, have documented inflated AWPs for generic drugs ***within the Medicare Part B context.*** Defendant

[11] Defendants' arguments to the contrary are improper on a motion to dismiss.

[12] In November 1998, and based on the OIG report, DHHS amended 42 C.F.R. § 405.517 to base multiple-source drug reimbursements on the lesser of (i) the median AWP for all generics or (ii) the lowest brand name AWP. *See* 63 Fed. Reg. 58,814, at 58,849-50 (Nov. 2, 1998).

Abbott, in particular, has been cited by DOJ for reporting inflated AWPs for its generic drugs reimbursed by Medicare Part B. For 2000 alone, DOJ cited at least 81 instances where the published AWPs for various dosages of 16 drugs manufactured by Abbott were substantially higher than the actual prices listed by wholesalers:

| Drug | Abbott's 2001 *Red Book* AWP | DOJ Determined Actual AWP | Difference | Percentage Spread |
|---|---|---|---|---|
| Acetylcysteine | $35.87 | $21.90 | $13.97 | 64% |
| Acyclovir | $1047.38 | $349.05 | $698.33 | 200% |
| Amikacin Sulfate | $995.84 | $125.00 | $870.84 | 697% |
| Calcitriol (Calcijex) | $1,390.66 | $1079.00 | $311.66 | 29% |
| Cimetidine Hydrochloride | $214.34 | $35.00 | $179.34 | 512% |
| Clindamycin Phosphate | $340.52 | $75.35 | $265.17 | 352% |
| Dextrose | $239.97 | $3.91 | $236.06 | 6,037% |
| Dextrose Sodium Chloride | $304.38 | $1.93 | $302.45 | 15,671% |
| Diazepam | $28.50 | $2.03 | $26.47 | 1,304% |
| Furosemide | $74.52 | $14.38 | $60.14 | 418% |
| Gentamicin Sulfate | $64.42 | $.51 | $63.91 | 12,531% |
| Heparin Lock Flush | $38.30 | $13.60 | $24.70 | 182% |
| Metholprednisolone Sodium Succinate | $34.08 | $2.30 | $31.78 | 1,382% |
| Sodium Chloride | $670.89 | $3.22 | $667.67 | 20,735% |
| Tobramycin Sulfate | $150.52 | $2.94 | $147.58 | 5,020% |
| Vancomycin Hydrochloride | $382.14 | $4.98 | $377.16 | 7,574% |

*See* ¶ 208 (citing PM Rev. AB-00-86, "An Additional Source of Average Wholesale Price Data In Pricing Drugs and Biologicals Covered by the Medicare Program," Sept. 8, 2000).

***And this argument ignores allegations that generic or multiple source manufacturers did compete on an AWP basis.*** *See, e.g.*, ¶¶ 278-80 (where Baxter, after acknowledging the existence of "deliberate manipulation of AWP" as a method to "increase product positioning," then "adjusted our AWPs to meet competitive levels"); ¶ 291 (Bayer increasing AWP on generic drugs to meet competition); ¶¶ 318-20 (B. Braun, after acknowledging that the practice was "scandalous, or worse, fraudulent," then evaluated its AWPs against Baxter's and Abbott's, and increased them to "make them equivalent."). ***Thus, Defendants have admitted in their own documents that they compete based upon AWP manipulation.*** It is therefore no wonder that their replies ignore these allegations.

Defendants' arguments thus steadfastly ignore these controlling allegations and studies. The Court should quickly reject Defendants' "flat rate" myth and sustain the AWP Inflation Scheme paradigm for multiple-source drugs reimbursed through Medicare Part B.

### 2. Multiple-Source Drug Manufacturers Over-Inflate AWPs to Push Product in the Private Sector

Turning next to private sector reimbursement systems, Defendants boldly proclaim that Plaintiffs "fail[] to explain reimbursement rules in the 'private payor arena,'" because Plaintiffs allege that reimbursement is merely "tied" to AWP. Defs. Reply at 19. This is a misstatement of both the AMCC and Plaintiffs' opposition brief.

The AMCC documents two reimbursement mechanisms for multiple-source drugs in the private payor arena. Generic drug reimbursement can be determined "in the same manner [as] for brand name drugs (*i.e.*, a certain percentage 'discount' off of the AWP)." ¶ 181. Alternatively, generic drug reimbursement can be determined based on maximum allowable cost or "MAC" lists, which are pricing schedules based on the listed AWPs of competing generic manufacturers. *Id.* PBMs frequently use MAC lists and calculate the MAC based on the average of AWPs reported by generic manufacturers. ¶ 182. Thus, the AMCC clearly explains the specific reimbursement rules that operate in the private payor arena – a far cry from the passing reference portrayed by Defendants.

Defendants next claim that the mere existence of a "spread" does not alone explain how competition based on AWP can exist for multiple source drugs. Defs. Reply at 19-20.[13] But Plaintiffs do not merely rely on the fact that there are "spreads" on generic drugs, even though the spreads are in many cases simply gargantuan.[14] The AMCC also explains that generic

[13] It is somewhat ironic that the generic manufacturing Defendants cry that alleging spreads is insufficient where, elsewhere, all Defendants contend that Plaintiffs must identify each drug and the specific spreads for those drugs in order to state a claim. Now that Plaintiffs have done so in the generic world where AWP inflation is most rampant, Defendants want to raise the pleading bar ever so higher.

[14] *See, e.g.*, ¶ 280 (41,167%, 12,108%, 54,199%); ¶ 311 (1,202%, 6,581%, 2,415%); ¶¶ 324-25 (601%, 660%, 1,063%, 1,260%); ¶ 343 (298%); ¶ 353 (488%); ¶ 360 (277%, 230%, 234%); ¶ 373 (885%, 528%, 970%), and so forth.

manufacturers ***compete*** on spreads, just like brand name manufacturers do. For instance, the AMCC alleges that:

> Generic drug makers are able to push market share for their generic drugs by intentionally increasing the published AWP for a generic drug with the intention to create a profit margin for others in the distribution chain. That profit margin is taken advantage of either directly (through reimbursement based upon the AWP for some plans and in some channels) or indirectly on the AWP based upon the establishment of a MAC tied to the AWP.

¶ 183. Further commenting on the mechanisms employed by generic manufacturers to promote their products through marketing spreads, the AMCC explains that "[e]ach Defendant generic maker or distributor competes by inflating its AWP and thereby inflating the median AWP. The natural and expected result of this 'leap frogging' of increasing AWPs is that multi-source drugs have some of the highest spreads of any drugs, sometimes resulting in an AWP over 50,000% over actual costs." ¶ 187.

Plaintiffs did not just divine the theory that generic manufacturers inflated their reported AWPs to create spreads and push product. As the AMCC alleges, one industry expert describes AWP inflation as "more pronounced with generic drugs," explaining that "[m]any generic companies have taken advantage of this use of AWP by substantially inflating their published AWPs...." ¶ 185. All of these allegations are completely ignored by Defendants.

And, perhaps, no one "makes the case" for the importance of creating and promoting "spreads" on generic drugs better than does Defendant Dey, Inc. In a lawsuit recently brought by Dey against two Publishers (*First DataBank* and *Medi-Span*) for purportedly publishing independently-derived AWPs for Dey generics instead of those reported by Dey, Dey acknowledged that private payors utilize AWP in their reimbursements for generic drugs. ¶ 189(c) (citing ¶ 13 of Dey Complaint). Moreover, Dey admitted that generic manufacturers are "cognizant of, and are highly attentive to, AWPs as reported ... because of the ***direct relationship*** between the level of reimbursement ... and the reported AWPs of these drugs." ¶ 189(e) (quoting ¶ 38 of Dey Complaint) (emphasis added). A reasonable inference of the word

"attentive to" in this context is that it refers to "competition." And contrary to Defendants' argument that the AWP Inflation Scheme makes no sense for generics manufacturers, Dey admits the exact opposite and confesses that competition occurs:

> Since reimbursement to Dey's customers is, in Medicaid program in many states ***and in and [sic] insurance programs***, most frequently based on the AWP as reported by the reporting services, this arbitrary and capricious reduction by First DataBank and Medi-Span in AWP would result in a drastic reduction in the reimbursement to drug providers who choose to dispense Dey's product. ***Since there has not been a comparable reduction in the AWP for Dey's competitors***, there would be no comparable reduction in the reimbursement the purchasers of competitive products receive.
>
> ***Because reimbursement for Dey products would be significantly reduced, but reimbursement for those competing products would remain as they have been, Dey is prevented, by First DataBank's and Medi-Span's arbitrary and capricious acts, from effectively competing in the marketplace.***
>
> ***In fact, within one day of learning that First DataBank and Medi-Span had arbitrarily changed Dey's AWP, Dey has already been contacted by at least nine of its customers complaining about the drastic changes and indicating that, because of those changes, the customers would not be able to purchase Dey products since they could not earn a reasonable profit from the sale of such products.***
>
> Further, at least one customer has already indicated that he had canceled all of his purchases presently on order from Dey and was, instead, buying those products from Dey's direct competitors.
>
> .... These providers will cease to purchase and dispense Dey's drugs if the reimbursement for those drugs is a fraction of those obtained from competing companies. Because purchasing decisions are highly concentrated in this industry among wholesalers and group purchasing organizations, this scenario is playing out across the country and threatens to eliminate sales of Dey's products that are covered by Medicaid and insurance reimbursement programs.

¶ 189(e) (quoting ¶¶ 50-54 of Dey Complaint) (emphasis added).

***Dey is thus admitting that without the use of inflated AWPs, like those of its competitors, it cannot compete; indeed, "within one day" of the truth being revealed that AWPs were not as inflated as Dey was reporting, Dey was losing customers.*** Dey's admissions

utterly belie the assertions made by all generic manufacturers that there is no economic reason to inflate AWPs on multiple source drugs.

Documents produced by other generic manufacturers establish that Dey is not the only Defendant who admits the importance of creating and promoting spreads for generic drugs in order to compete on reimbursements. For example, Abbott anticipated that the spread between AWP and cost might be eliminated by legislative changes in 1997. Accordingly, Abbott looked for ways to maximize the profit spread immediately. In one internal memorandum about a third party's pricing product, Abbott states:

> One of GeriMed's goals of obtaining maximum profitability for its members presents an opportunity for our injectables. They think there is about an 18 month window of opportunity to promote our injectables as more profitable for their members to use because of the bigger spread between AWP and cost. Legislative changes in reimbursement are expected to do away with this ***spread advantage*** by mid 1997.

¶ 205 (quoting document ABT AWP/MDL 015839) (Highly Confidential) (emphasis added)). In a second memorandum about this same product, Abbott states:

> The purpose of these programs was to "enhance revenue and decrease cost." *** These suggestions are made to save money through lower contract pricing or increase revenue through better spread between AWP and contract price.... The [distributor's] program identifies the lowest cost product and ***the best spread for the particular state***.

*Id.* (quoting document ABT AWP/MDL 010407-09) (Highly Confidential) (emphasis added)).

While other generic manufacturers do not use Abbott's precise "spread advantage" phraseology, they leave no doubt about the importance of creating and promoting spreads to sell more generic drugs. For example, an internal memorandum produced by Defendant B. Braun states:

> I evaluated each McGaw AWP against Baxter's and Abbott's and individually determined which AWPs should be increased.... In general, I raised the McGaw AWPs to make them equivalent to Baxter.

¶ 320 (quoting document BBMDL 009658) (Highly Confidential). A second memorandum, created in October of 1997, reveals that B. Braun subsequently performed an analysis to "assure that McGaw AWPs are in line with Baxter/Abbott AWPs on competitive products." An October 17, 1997 memorandum reveals that the company increased 54 separate AWPs following a review of 200 drugs to "make them equivalent to both Baxter and Abbott." *Id.* (quoting documents BBMDL 009763 and BBMDL 001891) (Highly Confidential).

Similarly, Defendant Fujisawa adjusted AWPs for its generic drugs to help its marketing efforts, as evidenced by the following memorandum:

> Many thanks to Rick and Bruce for adjusting the AWP on the five gram Vanco. This should lead to more business. As I have previously reported, some companies are still using AWP for reimbursement purposes. Chartwell has been told to search for the largest spread and order accordingly. I would have liked to see us match Abbott's AWP for our complete Vanco, and Cefazolin line. I will settle for the five gram at $1 below Abbott but that means that we still have to compete at the other end of the equation. For example, if Abbott's AWP is $163 and their contract is $30 and if our AWP is $162 we will have to be at least $29 to have the same spread. Follow?

¶ 368 (quoting document FY-MDL 005668-69) (Confidential).

Immunex also recognized the benefits obtained from inflating AWPs for its leucovorin and methotrexate generic drugs: "[d]ue to the 'spread' (difference between acquisition cost and AWP), physicians have reaped substantial profits." ¶ 427 (quoting document IAWP051149-52) (Highly Confidential).

Incredibly, Defendants do not even attempt to address any of these allegations. They ignore the Dey suit allegations and the many other admissions chronicled above that directly establish the link between AWP inflation for generic drugs and inflated drug reimbursements. If "spreads" for generic drugs did not matter, Defendants would not have promoted the "spread advantage" and written the documents cited in the AMCC and referenced above. Any conclusion to the contrary would not only run counter to Plaintiffs' controlling allegations, it would also be illogical given these facts. The Court should reject Defendants' bankrupt

argument and sustain the AWP Inflation Scheme paradigm for multiple-source drugs reimbursed by private payors.

### F. In Their So-Called "Defendant-Specific Replies," Defendants Fail To Present Any Viable Arguments Supporting Dismissal Of Any Individual Defendant

In addition to their 20-page common brief, Defendants filed 60 pages of "individual" reply memoranda. In order to avoid the 20-page limitation placed on the consolidated reply memorandum, Defendants' merged common issues into their Defendant-"specific" replies, as they did in their original supporting memoranda. Enough is enough. By any measure of fairness, the Court should disregard any arguments found in individual replies that appear to be "common" to all Defendants as opposed to truly specific to the particular Defendant. To assist the Court in making this determination on a Defendant-by-Defendant basis, in Exhibit A hereto Plaintiffs identify the improper arguments that should be stricken or otherwise disregarded by the Court.

It is not possible in the 40 pages allotted to Plaintiffs here to respond to both the common memorandum and even the truly "Defendant-specific" arguments made in the 19 individual memoranda. However, in the limited space remaining below, Plaintiffs rebut some of the arguments contained in the individual replies. To the extent that Plaintiffs cannot respond to each argument made, Plaintiffs' "silence" on these matters – borne of tight space limitations and Defendants' patent abuse of their right to present individual arguments – should not be construed as any concession. Accordingly, in addition to the remaining argument below, Plaintiffs refer the Court to their previous opposition memoranda.

#### 1. Generic/Multiple Source Drugs

All of the generic or multiple source manufacturers assert that the AWP Inflation Scheme cannot occur in the generic market. These non-defendant-specific arguments have been addressed above.

**2. 9(b) Is Satisfied**

Several Defendants repeat their mantra that specification of the fraudulent AWP in Appendix A does not comply with Rule 9(b). This argument was adequately addressed in Plaintiffs' Consolidated Opposition (6-10), and Defendants' arguments add nothing new.

**3. Where Plaintiffs Have Purchased at Least One Drug From a Defendant, Standing Is Established for All Drugs**

Various Defendants all claim that if Plaintiffs purchased some but not all drugs listed in Appendix A, those drugs not purchased must be dismissed from the case. This issue was addressed in detail in Plaintiffs' Separate Opposition to Defendant-Specific Memoranda, under the discussion of juridical linkage, pages 13-16. Essentially, Plaintiffs have alleged that each Defendant manipulated the AWP for all of its drugs listed in Exhibit A of the AMCC in essentially the same manner. Thus, it is appropriate to allow a Plaintiff who has been harmed by a Defendant's fraud for one drug to represent a class of people who have been harmed by that Defendant's AWP fraud for all of its drugs. Defendants claim that this juridical link is improper, but the Court has already ruled that this argument "will be decided at a later stage." *AWP*, 263 F. Supp. 2d at 193-94. And, Defendants cannot distinguish *Weld v. Glaxo Wellcome, Inc.*, 434 Mass. 81, 91 (2001), where the Court found a juridical link to provide standing in similar circumstances. Nor can Defendants distinguish *Alves v. Harvard Pilgrim Health Care, Inc.*, 204 F. Supp. 2d 198, 205 (D. Mass. 2002), where the Court allowed a Plaintiff with a claim against one ERISA plan to represent a class of plaintiffs who were in other health plans with different sponsors. Defendants raise no new arguments on this subject in their individual Reply Memoranda.

**4. The Associations Are Not Proper Plaintiffs to this Litigation**

Plaintiffs agree that an Association has no standing to bring claims against a Defendant for which the Association does not allege a purchase of any drug from that Defendant by any of the Association's members.

**5. The Complaint Does Not Need to Identify Competitors**

Abbott and TAP (which is 50 percent owned by Abbott) raise the identical argument that the theories of the AMCC make no economic sense outside the Medicare Part B context. Both Defendants now assert that Plaintiffs must identify competitors for all drugs in the AMCC outside the Part B context and detail the nature of the competition. Abbott and TAP cite to no authority requiring such a showing, much less requiring it at this preliminary stage of the proceedings. Nothing in the Court's May 13, 2003 Order requires the identification of competitors for all drugs included in the AMCC, and to the extent it was raised earlier, which it was not, it was rejected by the Court.

**6. Boehringer's Argument that the AMCC Violated Local Rule 15.1 is Silly**

Boehringer argues that Plaintiffs' inadvertent violation of Local Rule 15.1, which requires 10 days' notice to a party before filing an Amended Complaint, has harmed Boehringer because Boehringer is "denied the opportunity to adequately prepare a defense ..." Plaintiffs note that the AMCC was filed June 12, 2003. Since that time no discovery has been conducted against Boehringer, and the only action involving Boehringer has been the filing of motions to dismiss. It is impossible to imagine how Boehringer has been prejudiced, or would have acted any differently, because it did not receive the additional 10 days notice contemplated by Local Rule 15.1. Plaintiffs respectfully submit that Boehringer's protest that it has been harmed by the Plaintiffs' failure to comply with Local Rule 15.1 falls into the category of arguments which this Court has previously labeled as "detritus."

As to Boehringer's argument that it does not know which of the underlying constituent actions it has been named a Defendant in, Plaintiffs suggest that this is yet another attempt to create an issue where none exists. Boehringer's concern is, at best, theoretical. If, at some point in the future it is determined that the MDL proceedings are concluded and the constituent actions should return to their home forums for trial, then any concerns Boehringer, or any other